(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 444 492 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
10.01.1996 Bulletin 1996/02

(51) Int. Cl.[6]: **A61K 31/725**

(21) Application number: **91102240.8**

(22) Date of filing: **18.02.1991**

(54) Topically administered compositions based on high molecular weight hyaluronic acid for treating inflammations of the oral cavity, and for oral cavity hygiene and cosmetic treatment

Topisch anwendbare Zusammensetzungen auf der Basis von hoch molekularer Hyaluronsäure zur Behandlung von Entzündungen der Mundhöhle, zu deren Hygiene und kosmetischer Behandlung

Compositions pour l'administration topique à base d'acide hyaluronique de haut poids moléculaire pour traiter les inflammations de la cavité buccale, pour l'hygiène de la cavité buccale et comme traitement cosmétique

(84) Designated Contracting States:
DE ES FR GB GR IT

(30) Priority: **21.02.1990 IT 1943890**

(43) Date of publication of application:
04.09.1991 Bulletin 1991/36

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Remarks:
The file contains technical information submitted after the application was filed and not included in this specification

Printed by Rank Xerox (UK) Business Services
2.9/3.4

EP 0 444 492 B1

EXAMPLE 7 Adhesive paste for dentures

An adhesive paste for dentures is prepared by mixing the following components in the indicated proportions:

sodium hyaluronate (average M.W. 1,500,000)	0.2%
lidocaine	4 %
phenol	0.1%
white vaselin	57.7%
high viscosity sodium carboxymethylcellulose	22 %
liquid paraffin	8 %
cholesterol	2 %
stearyl alcohol	3 %
anhydrous alcohol	3 %

The gingival paste prepared in Example 2 containing 0.2% of sodium hyaluronate of average molecular weight 1,500,000 was tested on 10 patients.

The chosen patients showed various degrees of parodontal pathology. The first group comprising 6 patients suffered from simple marginal gingivitis, whereas the second group comprising the remaining 4 patients had undergone parodontal surgery.

With the first group it was noted that the topical use of the gingival paste containing hyaluronic acid resulted always by the second day in a reduction in symptomatology, characterised essentially by hypersensitivity to heat stimuli and slight bleeding on brushing, with complete recovery within one week.

With the second group examined, recovery was slower due essentially to the fact that a surgical wound was present which alone required about one week for recovery.

For this reason the compound was applied only during the latter stages of recovery mainly because the wound was protected by a parodontal compress. A clear improvement in condition was also noted in this group, to the extent that on termination of treatment the mucosa at the wound level was trophic and pink-coloured.

In conclusion the product was of considerable help in recovery, in that with the first group it participated in normal oral hygiene and with the second group it facilitated the normal physiological reparation processes.

Tests were conducted on the same patients with other compositions deriving from the aforesaid examples, the results obtained being comparable with those described.

Claims

Claims for the following Contracting States : DE, FR, GB, IT

1. Use of hyaluronic acid in the form of its sodium salt, characterised by an average molecular weight of between 800,000 and 4,000,000, as active principle in the preparation of pharmaceutical compositions for topical application both for the therapy and prophylaxis of inflammatory affections of the oral cavity, and for oral cavity hygiene and cosmetic treatment, on condition that said compositions do not contain any compound selected from the group consisting of methyl salicylate, sodium salicylate, benzyl alcohol, oleic acid, propylene glycol, sodium glycolate, polyoxyethylen-10-cethyl ether, sodium-ethylenediaminetetraacetic acid (EDTA), sodium dodecylsulphate and dimethylsulphoxide (DMSO).

2. The use of hyaluronic acid in the form of its sodium salt as claimed in claim 1, characterised in that the average molecular weight of the hyaluronic acid is between 1,000,000 and 2,000,000.

3. Topical compositions containing the sodium salt of hyaluronic acid as the sole active principle in accordance with one of the preceding claims in combination with excipients, for the therapeutic and prophylactic treatment of inflammatory affections of the oral cavity, and for oral cavity hygiene and cosmetic treatment, on condition that said compositions do not contain any compound selected from the group consisting of methyl salicylate, sodium salicylate,

benzyl alcohol, oleic acid, propylene glycol, sodium glycolate, polyoxyethylen-10-cethyl ether, sodium-ethylenediaminetetraacetic acid (EDTA), sodium dodecylsulphate and dimethylsulphoxide (DMSO).

4. The topical compositions as claimed in claim 3, containing the active principle in amounts ranging from 0.005 to 10% by weight based on the total composition weight.

5. The topical compositions for the therapeutic treatment of inflammatory affections of the oral cavity as claimed in claim 4, containing the active principle in amounts ranging from 0.2 and 10% by weight based on the total composition weight.

6. The topical compositions for the therapeutic treatment of inflammatory affections of the oral cavity as claimed in claim 5, containing the active principle in amounts ranging from 0.2 and 1% by weight based on the total composition weight.

7. The topical compositions for the prophylaxis, cosmetic treatment and hygiene of the oral cavity as claimed in claim 4, containing the active principle in a concentration of between 0.005 and 0.1% by weight based on the total composition weight.

8. The topical compositions as claimed in claim 7, containing the active principle in a concentration of 0.01% by weight, based on the total composition weight.

9. The compositions as claimed in claim 3, in the form of gingival pastes, toothpastes, mouthwashes, adhesive pastes and powders.

10. The topical compositions as claimed in one of claims 5 and 6 for the treatment of gingivitis, stomatitis and irritation due to mechanical causes or surgery.

11. Gingival pastes as claimed in claim 9 for the dentition stage in children.

Claims for the following Contracting States : ES, GR

1. A process for the preparation of compositions for topical application both for the therapy and prophylaxis of inflammatory affections of the oral cavity, and for oral cavity hygiene and cosmetic treatment, containing the sodium salt of hyaluronic acid of average molecular weight of between 800,000 and 4,000,000 as the sole active principle, in combination with excipients, on condition that said compositions do not contain any compound selected from the group consisting of methyl salicylate, sodium salicylate, benzyl alcohol, oleic acid, propylene glycol, sodium glycolate, polyoxyethylen-10-cethyl ether, sodium-ethylenediaminetetraacetic acid (EDTA), sodium dodecylsulphate and dimethylsulphoxide (DMSO), said process comprising admixing the active principle with the excipients.

2. The process as claimed in claim 1, characterised in that the average molecular weight of the hyaluronic acid is between 1,000,000 and 2,000,000.

3. The process as claimed in claim 1, characterised in that the active principle is in amounts ranging from 0.005 to 10% by weight based on the total composition weight.

4. The process as claimed in claim 1, characterised in that said compositions for the therapy of inflammatory affections of the oral cavity contain the active principle in amounts ranging from 0.2 and 10% by weight based on the total composition weight.

5. The process as claimed in claim 4, characterised in that said compositions for the therapy of inflammatory affections of the oral cavity contain the active principle in amounts ranging from 0.2 and 1% by weight based on the total composition weight.

6. The process as claimed in claim 3, characterised in that said compositions for prophylaxis of inflammatory affections, cosmetic treatment and hygiene of the oral cavity contains the active principle in a concentration of between 0.005 and 0.1% by weight based on the total composition weight.

7. The process as claimed in claim 6, characterised in that said compositions contain the active principle in a concentration of 0.01% by weight, based on the total composition weight.

8. The process as claimed in claim 1, characterised in that said compositions are in the form of gingival pastes, toothpastes, mouthwashes, adhesive pastes and powders.

9. The process as claimed in claim 4 or 5, characterised in that said compositions are useful for the treatment of gingivitis, stomatitis and irritation due to mechanical causes or surgery.

10. The process as claimed in claim 8, characterised in that said gingival pastes are useful during the dentition stage in children.

Patentansprüche

Patentansprüche für folgende Vertragsstaaten : DE, FR, GB, IT

1. Verwendung der Hyaluronsäure in der Form ihres Natriumsalzes, gekennzeichnet durch ein mittleres Molekulargewicht zwischen 800.000 und 4.000.000, als Wirkstoff bei der Herstellung von pharmazeutischen Zusammensetzungen für eine topische Verabreichung sowohl für die Therapie und Prophylaxe von entzündlichen Erkrankungen der Mundhöhle als auch für die Hygiene der Mundhöhle und eine kosmetische Behandlung, unter der Bedingung, daß die genannten Zusammensetzungen keine Verbindung enthalten, die aus der Gruppe ausgewählt ist, welche aus Methylsalicylat, Natriumsalicylat, Benzylalkohol, Ölsäure, Propylenglycol, Natriumglycolat, Polyoxyethylen-10-cetylether, Natriumsalz der Ethylendiaminotetraessigsäure (EDTA), Natriumdodecylsulfat oder Dimethylsulfoxid (DMSO) besteht.

2. Die Verwendung der Hyaluronsäure in der Form ihres Natriumsalzes, wie sie im Anspruch 1 beansprucht wird, dadurch gekennzeichnet, daß das mittlere Molekulargewicht der Hyaluronsäure zwischen 1.000.000 und 2.000.000 liegt.

3. Topische Zusammensetzungen, welche das Natriumsalz der Hyaluronsäure als alleinigen Wirkstoff gemäß einem der vorhergehenden Ansprüche in Kombination mit Vehikeln enthalten, für die therapeutische und prophylaktische Behandlung von entzündlichen Erkrankungen der Mundhöhle, und für die Hygiene der Mundhöhle und die kosmetische Behandlung, unter der Bedingung, daß die genannten Zusammensetzungen keine Verbindung enthalten, die aus der Gruppe ausgewählt ist, welche aus Methylsalicylat, Natriumsalicylat, Benzylalkohol, Ölsäure, Propylenglycol, Natriumglycolat, Polyoxyethylen-10-cetylether, Natriumsalz der Ethylendiaminotetraessigsäure (EDTA), Natriumdodecylsulfat und Dimethylsulfoxid (DMSO) besteht.

4. Die topischen Zusammensetzungen, wie sie im Anspruch 3 beansprucht sind, welche den Wirkstoff mit einem Gehalt im Bereich von 0,005 bis 10 Gew.%, bezogen auf das Gesamtgewicht der Zusammensetzung, enthalten.

5. Die topischen Zusammensetzungen für die therapeutische Behandlung von entzündlichen Erkrankungen der Mundhöhle, wie sie im Anspruch 4 beansprucht werden, welche den Wirkstoff mit einem Gehalt im Bereich von 0,2 bis 10 Gew.%, bezogen auf das Gesamtgewicht der Zusammensetzung, enthalten.

6. Die topischen Zusammensetzungen für die therapeutische Behandlung von entzündlichen Erkrankungen der Mundhöhle, wie sie im Anspruch 5 beansprucht werden, welche den Wirkstoff mit einem Gehalt im Bereich von 0,2 bis 1 Gew.%, bezogen auf das Gesamtgewicht der Zusammensetzung, enthalten.

7. Die topischen Zusammensetzungen für die Prophylaxe, kosmetische Behandlung und Hygiene der Mundhöhle, wie sie im Anspruch 4 beansprucht werden, welche den Wirkstoff in einer Konzentration zwischen 0,005 und 0,1 Gew.%, bezogen auf das Gesamtgewicht der Zusammensetzung, enthalten.

8. Die topischen Zusammensetzungen, wie sie im Anspruch 7 beansprucht werden, welche den Wirkstoff in einer Konzentration 0,01 Gew.%, bezogen auf das Gesamtgewicht der Zusammensetzung, enthalten.

9. Die Zusammensetzungen, wie sie im Anspruch 3 beansprucht werden, in der Form von Zahnfleischpasten, Zahnpasten, Mundwässern, Haftpasten und Haftpulvern.

10. Die topischen Zusammensetzungen, wie sie in einem der Ansprüche 5 und 6 beansprucht werden, für die Behandlung von Gingivitis, Stomatitis, von Reizungen aufgrund mechanischer Ursachen oder aufgrund von Operationen.

11. Zahnfleischpasten, wie sie im Anspruch 9 beansprucht werden, für die Zahnung bei Kindern.